

Title 23: Division of Medicaid

Part 203: Physician Services

Part 203 Chapter 2: Physician-Administered Drugs and Implantable Drug System Devices

Rule 2.1: Covered Services

- A. The Division of Medicaid covers medically necessary physician-administered drugs and implantable drug system devices defined as a drug, other than vaccines, diagnostic or therapeutic radiopharmaceutical, contrast imaging agent, biological or implantable drug system device covered under the Social Security Act § 1927(k)(2) that:
 - 1. Are administered by a medical professional in a physician's office or other outpatient clinical setting,
 - 2. Are incident to physician services that are separately billed to the Division of Medicaid,
 - 3. Qualifies for rebate in accordance with 42 USC § 1396r-8, and
 - 4. Are Food and Drug Administration (FDA) approved or follows medically accepted indications and dosing limits supported by one (1) or more of the official compendia as designated by the Centers for Medicare and Medicaid Services (CMS).
- B. The Division of Medicaid reimburses for discarded drugs or biologicals up to the dosage amount indicated on the single-use vial or package label minus the administered dose(s) if:
 - 1. The drug or biological is supplied in a single use vial or single-use package,
 - 2. The drug or biological is actually administered to the beneficiary to appropriately address his/her condition and any unused portion is discarded,
 - 3. The amount wasted is recorded in the beneficiary's medical record,
 - 4. The provider has written policy and procedures regarding single-use drugs and biologicals and bills all payers in the same manner, and
 - 5. The amount billed to the Division of Medicaid as a discarded drug is not administered to another beneficiary or patient.
- C. The Division of Medicaid does not reimburse for discarded drugs or biologicals when:
 - 1. A beneficiary misses an appointment,
 - 2. A multi-use vial or package is used,
 - 3. The actual dose of the drug or biological administered is less than the billing unit,

4. The drug or biological is administered during an inpatient stay, or
 5. The extra amount of the drug is provided to account for wastage in a syringe hub.
- D. The Division of Medicaid defines an implantable drug system device as an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent or other similar or related article, including a component part, or accessory which is:
1. Recognized in the official National Formulary, the United States Pharmacopoeia or any supplement to one of these, or
 2. Intended for use in the diagnosing of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease.
- E. The Division of Medicaid covers the insertion and removal of a Food and Drug Administration (FDA) approved implantable drug system device if it:
1. Is medically necessary,
 2. Is in compliance with its approved uses, specifications and restrictions, and
 3. Meets all other applicable coverage requirements.
- F. The Division of Medicaid does not cover:
1. Services related to the use of a non-covered medical device, or
 2. Implantable drug system devices that are considered experimental or investigational.

Source: Social Security Act § 1927(k)(2); 42 USC § 1396r-8; Miss. Code Ann. § 43-13-121.

History: Revised eff. 07/01/2014.

Rule 2.2: Drug Rebates

- A. The Division of Medicaid collects Medicaid drug rebates from manufacturers on physician-administered drugs per the following:
1. Effective for all drugs administered on and after January 1, 2008, providers must submit the National Drug Code (NDC) in addition to the appropriate drug code for physician-administered drugs on claims.
 - a) An NDC is not required for vaccines or other drugs as specified by CMS.
 - b) The NDC must contain eleven (11) digits in the five (5) four (4) two (2) grouping

and, if applicable, include “leading zeros (0)” to constitute an eleven (11) digit NDC code.

- c) The NDC must be matched against a database to ensure its validity.
- 2. Providers reimbursed based on a fee-for-service must submit the NDC with the appropriate code(s) including, but not limited to, ambulances, independent radiology clinics, free-standing and hospital based dialysis facilities, nurse practitioners, optometrists, individual physicians, physician groups, physician assistants, and podiatrists.
- 3. Providers reimbursed based on a per diem, encounter or other type of rate are not required to submit the NDC or appropriate code(s) for drugs administered/dispensed by providers including, but not limited, to outpatient hospitals, federally qualified health centers (FQHC), rural health clinics (RHC), ambulatory surgical centers (ASC), home health agencies, nursing homes or other long term-term care facilities.
- 4. The Division of Medicaid only reimburses for physician administered drugs that are:
 - a) Subject to the federal rebate program, and
 - b) Not considered Drug Efficacy Study Implementation (DESI) drugs.
- 5. Providers participating in the 340B program must adhere to all the provisions in Miss. Admin. Code Part 200, Chapter 4, Rule 4.10.

Source: Deficit Reduction Act of 2005, Section 1927(a)(7) of the Security Act, Federal Regulations published by CMS on July 17, 2007; Miss. Code Ann. § 43-13-121.

History: Revised eff. 07/01/2014.

Rule 2.3: Botulinum Toxins A and B

- A. The Division of Medicaid covers Botulinum Toxin A and B injections when administered in accordance with Food and Drug Administration (FDA) approval or medically accepted indications and dosing limits supported by one of the following official compendia:
 - 1. American Hospital Formulary Service-Drug Information (AHFS-DI),
 - 2. United States Pharmacopoeia-Drug Information (USP-DI) or its approved replacement and/or successor publication, or
 - 3. The DrugDEX Information System.
- B. The Division of Medicaid covers Botulinum Toxin A when administered to treat the following diagnoses:

1. Facial Spasm,
2. Blepharospasm,
3. Hemifacial Spasm,
4. Cervical Dystonia,
5. Spasmodic Dysphonia,
6. Strabismus,
7. [Deleted eff. 07/01/2014]
8. Focal hand dystonia,
9. Chronic anal fissure with an unsatisfactory response to conservative treatment,
10. Esophageal achalasia in beneficiaries who have not responded to dilation therapy or who are poor surgical candidates,
11. Frey's syndrome,
12. Primary Axillary Hyperhidrosis that is inadequately managed with topical agents,
13. Spasticity to:
 - a) Relieve pain,
 - b) Assist with improving and stabilizing posture and walking,
 - c) Allow better range of motion,
 - d) Permit better response to physical therapy, and
 - e) Reduce severe spasms in order to provide adequate perineal and palmar hygiene,
14. [Deleted] Refer to Miss. Admin, Code Part 203, Rule 2.3.13.
15. Neurogenic detrusor overactivity in beneficiaries that have an inadequate response to or are intolerant of anticholinergic medication, and
16. Chronic migraine headaches occurring greater than fifteen (15) days per month with headaches lasting four (4) hours a day or longer.

- C. The Division of Medicaid covers Botulinum Toxin B to treat cervical dystonia.
- D. The Division of Medicaid reimburses for one (1) injection per each functional muscle group/anatomical site regardless of the number of injections made into each group/site or the number of muscles that comprises the functional group.
- E. The Division of Medicaid does not cover Botulinum toxin treatment for:
 - 1. Cosmetic reasons,
 - 2. Investigational use,
 - 3. Experimental purposes, or
 - 4. Continued use if two (2) consecutive treatments utilizing an appropriate or maximum dose failed to produce a satisfactory clinical response.
- F. Documentation must be maintained in the beneficiary's medical record including, but not limited to:
 - 1. Support for the medical necessity of the Botulinum Toxin injections and any prior treatments that were unsuccessful,
 - 2. A covered diagnosis,
 - 3. Type, dilution, strength and dosage of the injection and frequency of administration,
 - 4. Amount of drug wastage,
 - 5. Support for the medical necessity of electromyography procedures, if performed,
 - 6. Clinical effectiveness of all injections, and
 - 7. A complete description of the functional muscle group/anatomical site(s) injected.

Source: Miss. Code Ann. § 43-13-121.

History: Revised and added Miss. Admin. Code Part 203, Rule 2.3.A, B.15, B.16. and deleted Rule 2.3.B.7. eff. 07/01/2014.

Title 23: Division of Medicaid

Part 203: Physician Services

Part 203 Chapter 2: Injectable Drugs Physician-Administered Drugs and Implantable Drug System Devices

Rule 2.1: Covered Services

- A. The Division of Medicaid covers medically necessary physician-administered drugs and implantable drug system devices covers defined as a drugs, other than vaccines, diagnostic or therapeutic radiopharmaceutical, contrast imaging agent, injectable biological or implantable drug system device when administered in a clinically appropriate manner, covered under the Social Security Act § 1927(k)(2) that:
1. Are administered by a medical professional in a physician's office or other outpatient clinical setting,
 2. Are incident to physician services that are separately billed to the Division of Medicaid,
 3. Qualifies for rebate in accordance with 42 USC § 1396r-8, and
 4. Are Food and Drug Administration (FDA) approved or follows medically accepted indications and dosing limits supported by one (1) or more of the official compendia as designated by the Centers for Medicare and Medicaid Services (CMS).
- ~~1. The provider must submit claims for the units actually administered.~~
- ~~2. This rule is applicable to all providers billing injectable drugs.~~
- B. ~~The Division of Medicaid will not reimburse for discarded amounts of the drug when administered from a single use or multiple dose use vial. Providers cannot bill Medicaid beneficiaries for the discarded drug.~~
- B. The Division of Medicaid reimburses for discarded drugs or biologicals up to the dosage amount indicated on the single-use vial or package label minus the administered dose(s) if:
1. The drug or biological is supplied in a single use vial or single-use package,
 2. The drug or biological is actually administered to the beneficiary to appropriately address his/her condition and any unused portion is discarded,
 3. The amount wasted is recorded in the beneficiary's medical record,
 4. The provider has written policy and procedures regarding single-use drugs and biologicals and bills all payers in the same manner, and

5. The amount billed to the Division of Medicaid as a discarded drug is not administered to another beneficiary or patient.

C. The Division of Medicaid does not reimburse for discarded drugs or biologicals when:

1. A beneficiary misses an appointment,
2. A multi-use vial or package is used,
3. The actual dose of the drug or biological administered is less than the billing unit,
4. The drug or biological is administered during an inpatient stay, or
5. The extra amount of the drug is provided to account for wastage in a syringe hub.

DC. The Division of Medicaid defines an implantable drug system device as an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent or other similar or related article, including a component part, or accessory which is:

1. Recognized in the official National Formulary, the United States Pharmacopoeia or any supplement to one of these, or
2. Intended for use in the diagnosing of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease.

ED. The Division of Medicaid covers the insertion and removal of a Food and Drug Administration (FDA) approved implantable drug system device if it:

1. Is medically necessary,
2. Is in compliance with its approved uses, specifications and restrictions, and
3. Meets all other applicable coverage requirements.

FE. The Division of Medicaid does not cover:

1. Services related to the use of a non-covered medical device, or
2. Implantable drug system devices that are considered experimental or investigational.

Source: Social Security Act § 1927(k)(2); 42 USC § 1396r-8; Miss. Code Ann. § 43-13-121.

History: Revised eff. 07/01/2014.

Rule 2.2: Drug Rebates

B. The Division of Medicaid collects Medicaid drug rebates from manufacturers on physician-administered drugs per the following:

1. Effective for all drugs administered on and after January 1, 2008, providers must submit the National Drug Code (NDC) in addition to the appropriate drug code for physician-administered drugs on claims. ~~The Division of Medicaid defines physician-administered drugs as “covered outpatient drugs under 1927 (k) (2) of the Act (many are also covered under Medicare Part B) that are typically furnished incident to a physician’s service”.~~

~~a) This is applicable to all drugs including injectables, intravenous, biologicals, oral, radiological contrast agents, and compounded drugs.~~

~~b) An NDC must be submitted in addition to the appropriate drug code. Claims billed for these drugs without an NDC will be denied.~~

e)a) An NDC is not required for vaccines or other drugs as specified by CMS.

d)b) The NDC must ~~be contain~~ eleven (11) digits in the five (5) four (4) two (2) grouping and, if applicable, include. ~~Providers must enter “leading zeros (0)” (0) in order to constitute an eleven (11) digit NDC code.~~

e)c) The NDC must be ~~valid and is~~ matched against a database to ensure its validity.

2. Providers reimbursed based on a fee-for-service must submit the NDC with the appropriate code(s). ~~This includes providers such as including, but not limited to, ambulances, independent radiology clinics, free-standing and hospital based dialysis facilities, nurse practitioners, optometrists, individual physicians, physician groups, physician assistants, and podiatrists.~~

3. Providers reimbursed based on a per diem, encounter or other type of rate, ~~rather than a fee schedule~~, are not required to submit the NDC or appropriate code(s) for drugs administered/dispensed by providers including but not limited to . This includes providers such as inpatient-outpatient hospitals-providers, federally qualified health centers (FQHC), rural health clinics (RHC), ambulatory surgical centers (ASC), home health agencies, nursing homes or other long term-term care facilities, ~~and other providers that are paid on a per diem, encounter, or other type rate.~~

4. The Division of Medicaid only reimburses for physician administered drugs that are: ~~subject to a drug manufacturer rebate and not considered a Drug Efficacy Study Implementation (DESI) drug.~~

a) ~~Drugs that are not under~~ Subject to the federal rebate program, ~~will not be covered and~~

b) ~~Drugs that are~~ Not considered Drug Efficacy Study Implementation (DESI) drugs. ~~are not covered.~~

5. Providers participating in the 340B program must adhere to all the provisions in Miss. Admin. Code Part 200, Chapter 4, Rule 4.10.

Source: Deficit Reduction Act of 2005, Section 1927(a)(7) of the Security Act, Federal Regulations published by CMS on July 17, 2007; Miss. Code Ann. § 43-13-121.

History: Revised eff. 07/01/2014.

Rule 2.3: Botulinum Toxins A and B

A. The Division of Medicaid covers Botulinum Toxin A and B injections when administered in accordance with Food and Drug Administration (FDA) approval or medically accepted indications and dosing limits supported by one of the following official compendia:

1. American Hospital Formulary Service-Drug Information (AHFS-DI),
2. United States Pharmacopoeia-Drug Information (USP-DI) or its approved replacement and/or successor publication, or
3. The DrugDEX Information System.

A.B. The Division of Medicaid covers Botulinum Toxin A when administered to treat the following conditions diagnoses:

1. Facial Spasm,
2. Blepharospasm,
3. Hemifacial Spasm,
4. Cervical Dystonia (~~Torticollis~~),
5. Spasmodic Dysphonia,
6. Strabismus,
- ~~7. Nystagmus, [Deleted eff. 07/01/2014];~~
8. Focal hand dystonia,
9. Chronic anal fissure with an unsatisfactory response to conservative treatment,
10. Esophageal achalasia in patients beneficiaries who have not responded to dilation therapy or where who are poor surgical treatment is not indicated, candidates,

11. Frey's syndrome;
12. Primary Axillary Hyperhidrosis, that is inadequately managed with topical agents,
13. Spasticity to:
 - a) ~~(to reduce spasticity or excessive muscular contractions to~~ Relieve pain;
 - b) ~~to assist in~~ with improving and stabilizing postureing and walking;; ~~to~~
 - c) ~~a~~ Allow better range of motion; to
 - d) ~~p~~ Permit better response to physical therapy; and to
 - e) ~~r~~ Reduce severe spasms in order to provide adequate perineal and palmar hygiene),
14. ~~Spasticity in Cerebral Palsy, [Deleted] Refer to Miss. Admin. Code Part 203, Rule 2.3, 13.~~
15. Neurogenic Detrusor Overactivity in beneficiaries that have an inadequate response to or are intolerant of anticholinergic medication, and
16. Chronic Migraine Headaches: Occurring greater than fifteen (15) days per month with headaches lasting four (4) hours a day or longer.

~~B.C.~~ The Division of Medicaid covers ~~the use of~~ Botulinum Toxin B ~~when used~~ to treat cervical dystonia (~~torticollis~~).

~~C.D.~~ The Division of Medicaid reimburses for one (1) injection per each functional muscle group/anatomical site regardless of the number of injections made into each group/site or the number of muscles that composes the functional group.

~~D.~~ Botulinum toxin treatment is non-covered when used to manage the following conditions:

- ~~1. Chronic paralytic strabismus, except to reduce antagonist contractor in conjunction with surgical repair,~~
- ~~2. Strabismus when angles are over fifty (50) prism diopters,~~
- ~~3. Restrictive strabismus,~~
- ~~4. Duane's syndrome with lateral rectus weakness, or~~
- ~~5. Secondary strabismus caused by prior surgical over-recession of the antagonist.~~

~~E.~~ Botulin toxin treatment for cosmetic reasons such as craniofacial wrinkles is non-covered. The Division of Medicaid does not cover Botulinum toxin treatment for:

1. eCosmetic reasons,
2. Investigational use,
3. Experimental purposes or
4. Continued use if two (2) consecutive treatments utilizing an appropriate or maximum dose failed to produce a satisfactory clinical response.

~~F. Botulinum toxin treatment is contraindicated for patients receiving aminoglycosides and is a non-covered drug for patients with such contraindications.~~

~~G.~~ F. Documentation must be maintained in the patient/beneficiary's medical record that includes, but not limited to: the following elements:

1. Support for the medical necessity of the Botulinum Toxin injections and any prior treatments that were unsuccessful,
2. A covered diagnosis,
3. Type, dilution, strength and Dosage of the injection and frequency of administration the injections,
4. Documentation of quantity Amount of discarded portion of drug wastage,
5. Support for the medical necessity of electromyography procedures, if applicable performed,
6. Support for the eClinical effectiveness of all for subsequent injections if needed, and
7. Identification A complete description of the functional muscle group/anatomical site(s) injected.

Source: Miss. Code Ann. § 43-13-121.

History: Revised and added Miss. Admin. Code Part 203, Rule 2.3.A, B.15, B.16. and deleted 2.3.B.7. eff. 07/01/2014.